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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,993	06/27/2001	Kelly R. Brown	ETH-1567	3764

27614 7590 05/29/2009

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/892,993	BROWN ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 46-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 and 46-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks filed 2/18/2009. New claims 46-52 are added. Claim 26 is amended. Claims 27-45 are canceled. Claims 26 and 46-52 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/18/2009 has been entered.

Previous rejections and objections that are not reiterated herein are withdrawn.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 26 and 46-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

6. Claim 26 as amended and new claim 47 recite that the scaffold has "plurality of substantial parallel layers." Applicant has not pointed to portions of the specification that supports this new limitation and the examiner does not find the support in the specification as filed. While plurality of pores is present both the ceramic and polymer phases, even the figures supports at best three layers, a polymer layer, a ceramic layer and the interphase layer between the ceramic and polymer layers. Three layers do not provide antecedent support for the many/plurality of layers recited in amended claim 26 and new claim 47. Since plurality of layers was not envisioned by the originally filed specification, the recitation is new.

7. For claim 46, “plurality of porous polymer projections extending …” was not envisioned by the as filed specification.

8. The above rejection may be overcome by deleting limitations that are new to the original invention.

9. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. It is unclear what it means by "plurality of said plurality of extensions" in second to the last line of claim 46.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (US 6,376,573) in view of Ries et al. (US 4,623,553).

14. White teaches porous ceramic biomaterial in which polylactic acid or collagen is allowed to fill the pores of the ceramic (abstract). The starting porous ceramic (abstract; column 3, lines 5-22; column 4, lines 7-56) meets the requirement of claim 46 where a porous ceramic body is provided. The prepared gelatin solution (column 6, line 62, 63; column 8, lines 18-42) meets preparation of the polymer solution of claim 48); allowing the polymer solution to wick into the pores of the ceramic (Examples I-VI) meets the requirement for the polymer to infuse into the pores in claim 46. The wicking of the polymer solution into the pores of the ceramic is a mechanical or physical process and polymer and the ceramic interlock after the infusion. Furthermore, the polymer infused into the polymer pores is at a given depth and meets that limitation in the claim noting that no specific depth in centimeters or millimeters is claimed.

15. While the solvent in the case of Example I is removed in the vacuum oven, White does not teach lyophilization of the polymer infused ceramic, lyophilization is a known process for removing drying samples. For example, Ries dries ceramic products by lyophilization (see claim 1) . Therefore, taking the teachings of White and Ries, one having ordinary skill in the art would dry reasonably expect that the polymer infused ceramic can either be dried in vacuum oven or can be dried by lyophilization since the two process would equivalently produce dried product.

16. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000).

17. Claim 26 is a method of repairing a defect area at the gradient junction of cartilaginous tissue and bony tissues by using a composite laminate scaffold.

18. Niederauer describes the use of biodegradable multiphase scaffold for repair of articular cartilage (abstract); the multiphase scaffold comprises polymer and ceramic phases (Table 1 and 3rd and 4th full paragraphs, left column of page 2563) meeting the claimed scaffold having a ceramic and polymer phase; the phases are glued together using a solvent (page 2563, first three lines of text in right column) representing the discrete phases of scaffold of the claim 26. The construct of Niederauer is porous (see left column of page 2563) so that the porous nature of the polymer and ceramic phases are met and the also meets the plurality of pores claimed. Since the ceramic and polymer phases are placed next to each other, the phases would inherently communicate or interact at the interphase/junction region of the ceramic and polymer phases so that interaction between the phases is met; boring a receptacle space at the gradient junction of the site of injury as recited in claim 26 reads on the experimental design of Niederauer where defect sites are made in the right and left stifles and bilateral arthrotomies performed to place the implants (paragraph 2.4 at page 2564); the scaffold is implanted into the prepared knees. The interphase region between the polymer phase and the ceramic phase as claimed is the same region in Niederauer that is between the polymer phase and the ceramic phase. Niederauer is silent on placing the ceramic phase next to the bony tissue and placing the polymer phase next to the cartilage tissue. However, it is known in the art that ceramics closely resemble constituents of natural bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Niederauer to repair articular cartilage by placing the ceramic phase of the scaffold next to the bony tissue since the ceramic material closely resembles the bony tissue so that the bony tissue would grow into the ceramic tissue during the repair process.

19. Claim 47 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000).

20. Niederauer describes the use of biodegradable multiphase scaffold for repair of articular cartilage (abstract); the multiphase scaffold comprises polymer and ceramic phases (Table 1 and 3rd and 4th full paragraphs, left column of page 2563) meeting the claimed scaffold having a ceramic and polymer phase; the phases are glued together using a solvent (page 2563, first three lines of text in right column) representing the discrete phases of scaffold of the claim 47. The construct of Niederauer is porous (see left column of page 2563) so that the porous nature of the polymer and ceramic phases are met and the also meets the plurality of pores claimed. Since the ceramic and polymer phases are placed next to each other, the phases would inherently communicate or interact at the interphase/junction region of the ceramic and polymer phases so that interaction between the phases is met; the face of the polymer that is in direct communication with the ceramic phase is distal to the face that is not communicating with the ceramic; by the same token, the face of the ceramic that is communicating with the polymer phase distal to the other face removed from the polymer phase; the scaffold is implanted into the prepared knees. Because the solvent dissolves the interphase region between the polymer and the ceramic, the polymer extends into the pores of the ceramic and the ceramic extends into the pores of the polymer so that at the end, when the solvent has evaporated and the region is settled, there would be multiple extensions of polymer and ceramic into the pores of ceramic and polymer respectively to provide interaction that is representative of mechanical interlock between the ceramic and polymer phase because the interaction is physical, and not chemical.

The composite of claim 47 reads on the composite of Niederauer. The difference between claim 47 and Niederauer is that Niederauer does not specifically state that the polymer and ceramic phases are communicating via an interphase region. However, since the polymer and ceramic phases are attached to each other, the polymer and ceramic phases are communicating through that region of interaction. However, in the alternate, it would be reasonable to expect that the polymer and ceramic phases are interacting through the region of attachment where it is also reasonable expected that the polymer phase and the ceramic phase having been in contact with the solvent would dissolve at the interphase and undergo migration, the polymer into the ceramic and the ceramic into the polymer into the polymer. The interphase region between the polymer phase and the ceramic phase as claimed is the same region in Niederauer that is between the polymer phase and the ceramic phase. It therefore flows that the polymer and ceramic are interacting at the interphase region and are mechanically interlocked in view of the extensions into the polymer and into the ceramic.

21. Claims 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000) in view of Tomalia et al. (US 5,084,051).

22. Niederauer is described above to anticipate or render obvious claim 47. Niederauer scaffolds are loaded with cells (second full paragraph, left column of page 2562) meeting claim 50 and inclusion of growth factors, perichondrial cells in the scaffold (see introduction and second full paragraph, left column of page 2562) meet claim 49 . Since the polymer and ceramic layers are biodegradable in Niederauer, claim 51 is met. Regarding claim 52, the

scaffold exhibiting compositional transition in the interphase region is intrinsic, but because the ceramic and the polymer layers interact at the interphase region where the dissolved ceramic migrates into the pores of the polymer phase and the dissolved polymer migrates into the pores of the ceramic phase, a mechanical interlock ensues at the end of the migration after the solvent dries so that claim 52 is met.

23. Niederauer does not teach the limitations of claim 48 requiring mechanical reinforcement. But Tomalia discloses that porous polymer component of a biocomposite can be reinforced with fabric or with parallel or randomly oriented fibers and the reinforcement material can be made of resorbable materials such as polymer, copolymer, polymer mixture and/or ceramic material, fabric, non-woven gauches and short fibers (column 8, lines 57-67 and column 9, lines 45-52).

24. Therefore, taking the teachings of Niederauer in view of Tomalia, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that including fibers or felts or non-woven fabric or short fibers into the porous composite of Niederauer would reinforce the porous composite.

Response to Arguments

25. Applicant's arguments filed 2/18/2009 as the arguments apply to the current rejections have been fully considered but they are not persuasive.

26. Applicant argues Niederauer uses small amount of solvent to glue two polymer layers and that the three dimensional structure described in the currently amended claims from the polymer matrix-ceramic particles of Niederauer. The examiner disagrees because, Niederauer specifically states in paragraph 2.2 that the construct is a three layer device having a porous cartilage phase and a porous bone phase and a thin dense film on the articulating surface of the

cartilage phase that is a small amount; further, the use of small amount of solvent does not say that the phases will not dissolve, but the examiner's position is that the small amount of solvent would evaporate faster that larger amount being sufficient to effectively glue the phases together.

27. Applicant argues that Niederauer does not disclose infusion of polymer layer into the ceramic layer. The examiner agrees that Niederauer does not say that the polymer infuses into the ceramic layer, but because of the use of the solvent, albeit small, provides an environment for the polymer to respond to the solvent to effect the gluing of the phases, and in the process, any dissolved polymer will move/migrate into the pores in the ceramic that is in contact with the polymer.

28. Applicant also argues that any polymer that may infuse into the pores of the ceramic would solidify with out pores. The examiner disagrees because a porous structure would also give rise to porous end product in this case, and absent factual evidence any polymer infused into the pores of the ceramic would also be porous.

29. The examiner thanks applicant for the extensive amendment, but the amendment introduced new matter, and the product of claim 46 reads on the product of Niederauer, the process claim 46 is rejected over a new reference.

30. Although process claim 46 has been rejected over new art, amending the product claim 47 and process claims 26 and 46 so that the product in all the generic claims is recited as product by process to closely parallel process disclosed (see at least paragraphs [0071]-[0076] of the published application) will help the claims noting that the issues under 112 need to be overcome.

31. No claim is allowed .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618